K 050537

Summary of Safety and Effectiveness
Liquichek™ Cardiac Markers Plus Controls

1.0 Submitter

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Date of Summary Preparation

February 16, 2005

2.0 Device Identification

Product Trade Name:	Liquichek Cardiac Markers Plus Control Liquichek Cardiac Markers Plus Control LT Liquichek Cardiac Markers Plus Control LT Low
Common Name:	Multi-Analyte Controls, all kinds (Assayed and Unassayed)
Classifications:	Class I
Product Code:	JJY
Regulation Number:	CFR 862.1660

3.0 Device to Which Substantial Equivalence is Claimed

Liquichek™ Cardiac Markers Control LT
Bio-Rad Laboratories
Irvine, California

Docket Number: K040277

4.0 Description of Device

These products are prepared from human serum with added constituents of human and animal origin, preservatives and stabilizers. These controls are provided in liquid form.

5.0 Statement of Intended Use

6.0 Liquichek: Cardiac Markers Plus Control, Cardiac Markers Plus Control LT and Cardiac Markers Plus Control LT Low are intended for use as a quality control serum to monitor the precision of laboratory testing procedures listed in the package insert. These products do not contain sodium azide as a preservative. They contain a broad-spectrum anti-microbial cocktail as preservatives

where the concentration of any one ingredient is less than 0.1%. At this low level, these ingredients are not expected to cause a health hazard to the user. And thus, domestic and international regulations do not require this type of information on the vial or box label.

7.0 Comparison of the new device with the Predicate Device

Liquichek Cardiac Markers Plus Controls claims substantial equivalence to the Liquichek™ Cardiac Markers Control LT currently in commercial distribution. The new Liquichek Cardiac Markers Plus Controls contain B-type Natriuretic Peptide (BNP), Creatine Kinase, Total and C-Reactive Protein (CRP). The current product does not contain these analytes.

Table 1. Similarities and Differences between new and predicate device.

Characteristics	Bio-Rad Liquichek™ Cardiac Markers Plus Controls (New Device)	Bio-Rad Liquichek™ Cardiac Markers Control LT (Predicate Device K040277)
Similarities		
Intended Use	Liquichek Cardiac Markers Plus Controls are intended for use as a quality control serum to monitor the precision of laboratory testing procedures listed in the package insert.	Liquichek Cardiac Markers Control LT is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures listed in the package insert.
Form	Liquid	Liquid
Matrix	Human serum based	Human serum based
Differences		
Storage (Unopened)	–20°C to -70°C Until expiration date	–20°C or colder Until expiration date
Open Vial Claim	20 days at 2-8°C	All analytes 10 days except NT-proBNP 5 days at 2-8°C
Analytes	Contains: B-type Natriuretic Peptide (BNP) Creatine Kinase, Total C-Reactive Protein (CRP) CK-MB Isoenzyme Digitoxin Homocysteine Myoglobin N-terminal pro-B-type Natriuretic Peptide (NT-pro BNP) Troponin I Troponin T	Contains: CK-MB Isoenzyme Digitoxin Homocysteine Myoglobin N-terminal pro-B-type Natriuretic Peptide (NT-pro BNP) Troponin I Troponin T Does not contain B-type Natriuretic Peptide (BNP) Creatine Kinase, Total C-Reactive Protein (CRP)

8.0 STATEMENT OF SUPPORTING DATA

Stability studies have been performed to determine the open vial stability and shelf life for the Liquichek™ Cardiac Markers Plus Control. Product claims are as follows:

8.1 Open vial: All analytes will be stable for 20 days at 2 to 8°C.

8.2 Shelf Life: 3 years at -20°C to -70°C

8.3 Real time studies will be ongoing to support the shelf life of this product.

All supporting data is retained on file at Bio-Rad Laboratories.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 27 2005

Ms. Suzanne S. Parsons
Regulatory Affairs Specialist
Bio-Rad Laboratories, QSD
9500 Jeronimo Road
Irvine, CA 92618-2017

Re: k050537
Trade/Device Name: Liquichek™ Cardiac Markers Plus Control
Liquchek™ Cardiac Markers Plus Control LT
Liquichek™ Cardiac Markers Plus Control LT Low
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality Control Material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJY
Dated: February 22, 2005
Received: March 2, 2005

Dear Ms. Platt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Jean M. Cooper MS, DVM

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050537

Device Name: **Liquichek™ Cardiac Markers Plus Control**

Indications For Use: **Liquichek Cardiac Markers Plus Control is intended for use as a quality control serum to monitor the precision of laboratory testing procedures listed in the package insert.**

Device Name: **Liquichek™ Cardiac Markers Plus Control LT**

Indications For Use: **Liquichek Cardiac Markers Plus Control LT is intended for use as a quality control serum to monitor the precision of laboratory testing procedures listed in the package insert.**

Device Name: **Liquichek™ Cardiac Markers Plus Control LT Low**

Indications For Use: **Liquichek Cardiac Markers Plus Control LT Low is intended for use as a quality control serum to monitor the precision of laboratory testing procedures listed in the package insert.**

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K050537